REMARKS

Claim Status

Claims 36, 38, 41-44, 46 and 48 are pending. Claims 36 and 43 have been amended to recite a specified level of water. Support for the amount of water is found at page 16, lines 24-26

Claims 1-35, 37, 39-40, 45 and 47 were previously canceled without prejudice.

It is believed these changes do not involve any introduction of new matter. Consequently, entry of these changes is believed to be in order and is respectfully requested.

Rejection Under 35 USC §103(a) Over US Patents 5,589,160 and 5,658,553

Claims 36, 38, 41-44, 46, and 48 are rejected under 35 USC §103(a) as being unpatentable over either US Patent 5,589,160 (hereinafter referred to as '160) or US Patent 5,658,553 (hereinafter referred to as '553) both to Rice. The Applicant respectfully traverses the rejections to the extent they apply to the claims as now amended.

The Applicant respectfully asserts that the rejections are inapposite because the cited documents are from a non-analogous art. See MPEP 2141.01(a). In order for a reference to be "analogous", the reference must either be in the field of the Applicant's endeavor, or be reasonably pertinent to the particular problem with which the invention was concerned. Both cited documents relate to toothpastes and thickened compositions. See Column 8, lines 20-29 of '160. It is generally recommended and recognized that one does not ingest toothpaste. Toothpastes therefore would not be in the same field as swallowable liquid compositions that contain pharmaceutical actives. Accordingly, one of skill in the art of liquid, swallowable compositions that contain pharmaceutical actives would not look to non-ingestible toothpaste art to solve problems associated with delivery of pharmaceutical actives in swallowable, liquid compositions.

Even assuming, *arguendo*, tha t'160 and '553 were properly citable against the claimed in vention, those documents do not teach or suggest all of the claim limitations of Claims 36, 38, 41-44, 46 and 48, and therefore, the Examiner has failed to establish a *prima facie* case of obviousness. "To establish *prima facie* obviousness of a claimed

invention, all the claim limitations must be taught or suggested by the prior art." MPEP § 2143.03 citing *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). "All words in a claim must be considered in judging the patentability of that claim against the prior art." MPEP § 2143.03 citing *In reWilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970).

The '160 and '553 documents disclose abrasive dentifrice compositions. Contrary to the Examiner's assertions, neither document discloses or teaches anything with respect to oral, mucoretentive, aqueous *liquid* pharmaceutical compositions that contain about 70% to about 95% water.

There is no teaching or suggestion in either cited document for water levels in the range recited in the claims, as amended. Neither document teaches or suggests amounts of water above 50%, (see Column 8, lines 12-19), nor is there motivation for greater levels of water as the compositions of the cited documents are toothpastes, not liquids.

The compositions of '160 and '553 are abrasive and used to brush teeth and remove plaque. The Applicant's invention is swallowable and used to deliver pharmaceutical actives to and through mucus membranes. Neither cited document teaches or suggests anything with respect to a swallowable, *liquid*, mucoretentive composition.

In addition, the Examiner states that because the instant specification states that the acceptable forms of silicone dioxide include gels, precipitated silicon dioxide, etc. (page 8, lines 32-35), the silica precipitate of Rice reads on the recited component. Further, the Examiner admits that the cited documents only teach a suitable particle size range of from 5 to 11 microns. Yet, the Examiner further states that nowhere in the documents does it state that particle size below 5 microns is not suitable. The Examiner then asserts that the Applicant has not established any criticality with respect to the claimed particle sizes of less than 1 micron. The Applicant disagrees.

Based on the teachings in '160 and '553, one would have to carefully select potential silicas so that they would not damage the oral tissues, yet would be sufficiently large and abrasive to clean teeth and remove plaque. The Examiner asserts that nowhere in the documents does it state that particle size below 5 microns is not suitable. However,

the documents go to great lengths to describe the specific, desired characteristics of the particles in terms of size, hardness, abrasiveness, etc. Thus, the 5-11 micron range is particularly important and the cited documents require a particle size of 5-11 microns, for specific reasons.

The Applicant uses a particle size of less than one (1) micron also for particular, but different, reasons. The Examiner asserts that the Applicant teaches no "criticality" for the selected particle size. The Applicant is interested in the particulate component providing a mucoadhesive benefit. See the specification, page 4, lines 29-36, page 6, lines 31-36, and page 8, lines 31 to the end, to page 9, line 4. For example, the last two lines of page 4 state that the small particle size increases surface area for improved adsorption or bridging of the particle to mucin. Thus, the Applicant actually does teach why a particle size below 1 micron is beneficial.

The '160 and '553 documents are interested in the particulate component being abrasive. The particle size of 5-11 microns for abrasion as described in the cited documents does not teach or suggest in any way the Applicant's particle size of less than 1 micron for mucoretentiveness.

The Examiner further states that Examples I-III of '160 and '553 teach silica in the same amounts as claimed. In addition, the Examiner states that the cited compositions further comprise "pharmaceutically acceptable carriers" such as a surfactant, chelating agents such as sodium citrate, and preferably citric acid (col. 6, lines 58-67) in the same amounts as claimed in the instant application.

The Applicant disagrees. The definition of the type of carrier used in '160 is that of an "orally-acceptable *dentifrice* carrier" which is defined therein as meaning a suitable vehicle which can be used to apply the compositions to the oral cavity in a safe and effective manner. (See column 2, lines 51-54 of '160, and column 2, lines 56-59 of '553.) The compositions of '160 are not swallowable, ingestible, liquid pharmaceutical compositions. The are only delivered to the oral cavity. One does not generally swallow toothpaste. Thus, an "orally-acceptable dentifrice carrier" teaches nothing with respect to a pharmaceutically acceptable carrier for swallowing and ingesting.

The Examiner further states that the compositions of '160 and '553 are used for preventing tooth stain or removing plaque, are applied as a toothpaste, and thus meet the claimed limitations "oral, mucoretentive".

The Applicant disagrees. When the Examiner states that the compositions of '160 and '553 meet the claimed limitations "oral, mucoretentive", the Examiner is making a jump that is in no way taught or suggested by the documents. The cited documents do not teach or suggest anything with respect to a mucoretentive composition. The cited documents disclose toothpaste. Teeth are not mucus membranes. The present specification, at page 5 defines mucoretentive as having a degree of resistance to the normal physiological propulsive mechanism involving both longitudinal and circular muscle fiber contraction, which transports substances through the gastrointestinal tract, i.e. resistance to peristalsis. Thus, mucoretentive, as defined in the specification, refers to a composition's degree of resistance to washing and dissolving forces of fluids in the gastrointestinal tract. See page 5, lines 11-15 of the specification.

In contrast, the compositions of '160 would not likely remain on the oral tissues for extended periods of time. At column 1, lines 20-25 it is stated: "When preparing synthetic precipitated silicas, the objective is to obtain silicas which provide maximal cleaning with minimal *damage to oral tissue*." The abrasive compositions of '160 and '553 can be damaging to soft oral tissue and thus would not be intended for application to oral tissues or for ingestion. They are intended for application to teeth, and thus are not "oral, mucoretentive" compositions.

The Examiner also asserts that the cited documents teach flavoring agents (col. 7, lines 60-67) that read on the claimed sensory agents. Neither '160 nor '553 teach sensory agents in an oral liquid composition that includes or delivers a pharmaceutical active.

The Examiner also admits that neither document requires citric acid, but teaches it only as an optional ingredient. However, the Examiner asserts that both documents teach citric acid and other chelating agents for their efficiency in *removing plaque*, and that including a chelating agent such as citric acid or sodium citrate in the composition of '160 or '553 containing silicon dioxide and an active agent, with an expectation to increase the plaque removing effect of the dentifrice compositions, would have been within the scope of the skilled artisan

Including a chelating agent with an expectation to increase the plaque removing effect of toothpaste compositions may be within the scope of the skilled dentifrice or toothpaste artisan. However, teaching that a chelating agent removes plaque more effectively, or teaching how a chelating agent removes plaque, is irrelevant to how or why a chelating agent may be useful for an oral, mucoretentive, aqueous liquid, pharmaceutical composition that is swallowed and ingested. One of skill in the art relating to mucoretentive, aqueous liquid, pharmaceutical compositions that are swallowed would not look for guidance to a toothpaste composition that contains a chelating agent used to remove plaque and that is not swallowed. Nor would one of skill in the art be taught anything by the cited documents regarding use of a chelating agent in a swallowable mucoretentive aqueous liquid, pharmaceutical composition.

Finally, the Examiner states that absent any evidence to the contrary the composition of '160 and '553 possesses the property of retention of mucosal membranes because the composition is directed to an oral application.

The Applicant disagrees. Not all oral compositions are the same and absence of evidence to the contrary is not the standard for an obviousness rejection. Affirmative teaching or suggestion is required. Thus, because the cited documents teach or suggest nothing with respect to mucoretentiveness, and in fact state that their compositions are dentifrice compositions and are formulated so as not to damage the oral tissues, thus are likely not intended for application to the soft oral tissues, the cited documents do not teach or suggest that the compositions possess any property of retention on mucosal membranes.

Therefore, there is no suggestion or motivation present in '160 or '553 that would lead one of skill in the art to modify the teachings in Rice '160 or Rice '553 to arrive at the present invention. Therefore, the Applicant contends that the claimed invention is unobvious and that the rejections should be withdrawn.

Conclusion

In light of the above remarks, it is requested that the Examiner reconsider and withdraw the rejections under 35 USC §103(a). Early and favorable action in the case is respectfully requested.

This response represents an earnest effort to place the application in proper form and to distinguish the invention as now claimed from the applied references. In view of the foregoing, reconsideration of this application, entry of the amendments presented herein, and allowance of Claims 38, 38, 41-44, 46 and 48 is respectfully requested.

Respectfully submitted,

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